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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,661	03/22/2001	Rodney Rothstein	56615-A-PCT-US/JPW/AJM/WW	2135

7590 11/16/2004

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,661	ROTHSTEIN ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15,17-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,17-19 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 16 and 20 have been canceled. Claims 14 and 21 have been amended. Claims 1-15, 17-19, and 21-36 are pending. Claims 1-13 and 24-36, drawn to non-elected inventions, are withdrawn from consideration. Claims 14, 15, 17-19 and 21-23 are under consideration.

2. Claims 14, 15, 17-19 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14, 15 and 17-19 are method claims dependent on the identity of the a compound determined to mimic the binding of the SML1 protein of SEQ ID NO:2 to the large subunit of ribonucleotide reductase. Claims 21-23 are product claims dependent upon the identification of a fragment of Sml1 through the method of claim 14. The specification provides a written description of Sml1 as SEQ ID NO:2 wherein said protein inhibits the activity of ribonucleotide reductase (page 54 under the heading "Interaction between yeast Rnr1 protein and Sml1 protein" and page 56 under the heading "Inhibition of mouse ribonucleotide reductase by the Sml1 protein"). The specification states on page 54, lines 19-24, "nonapeptides from the C terminus of Rnr2p or Rnr4p inhibited the in vivo yeast RNR assay to about the same extent with and Ic50 of 44 and 30 uM, respectively. In contrast the nonapeptide corresponding to the C terminus of Sml1p showed an inhibition with an IC50 of only about 300 uM". Thus, it appears that the nonapeptide derived from the C-terminus of Sml1 would not be capable of reducing the division rate of a cell by binding and effectively inhibiting ribonucleotide reductase. The specification does not provide a written description of any fragments of Sml1 which are capable of reducing the division rate of a cell by means of mimicking the binding of full length Sml1 to ribonucleotide reductase. One of skill in the art would reasonably conclude that applicant was not in possession of claims 21-23. Further, claims 14, 15 and 17-19 are method claims reliant on the identity of "a compound" which has been determined to mimic the binding of Sml1 to ribonucleotide reductase. The term compounds encompasses a genus of molecules having highly variant structures. The contemplation of a fragments of Sml1 as a mimic of ribonucleotide

reductase binding by Sml1 does not adequately describe the claimed genus of "compounds" because said genus tolerates individual members having no structural relationship to Sml1. One of skill in the art would reasonably conclude that applicant was not in possession of claims 14, 15 and 17-19 because a method claim which relied on a product which is not adequately described cannot itself be adequately described.

3. Claims 14, 15, 17-19 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

The requirements of 112, first paragraph include that one of skill in the art should be able to make and use the instant invention without undue experimentation and with reasonable expectation of success. In order to proactive the method of claim 14 one of skill in the art must be able to make a compound determined to mimic the binding of Sml1 protein to the large subunit of ribonucleotide reductase. Said compounds encompass organic compounds, inorganic compounds, lipids, peptidomimetics, a fragment of a Sml1 protein or a synthetic compounds as evidenced by claim 15. Further, in order to function as claimed in the reduction of cell division, said compounds must compete with Sml1 full length for binding to ribonucleotide reductase, and exert an inhibitory effect on ribonucleotide reductase. The specification does not provide a single example of a compounds which mimics the binding of Sml1 to ribonucleotide reductase, nor does the specification provide an example of a compound which binds to ribonucleotide reductase and exerts an inhibitory effect thereon. The specification states that the Sml1 protein is about 200 times more efficient in inhibiting Rnr1 activity than the C-terminal nonapeptide (page 58, lines 27-29). Thus, it would be reasonably concluded that the nonapeptides would not be able to effectively elicit a decrease in the activity of ribonucleotide reductase necessary for limiting the growth of a cell. The specification fails to provide an element of structure within a compounds necessary for the reduction of the division rate of a cell, or specific examples of compounds which mimic the binding of Sml1 to ribonucleotide reductase and result in the inhibition of cell division. Given the lack of teachings in the specification regarding how to make compounds which have the claimed characteristics, one of skill in the art would be subject

to undue experimentation without reasonable expectation of success in order to carry the instant methods. Further, one of skill in the art would not be assured that a fragment of Sml1 exist which can bind to the large subunit of ribonucleotide reductase and reduce the division rate of a cell, because it would be necessary to efficiently bind to ribonucleotide reductase, and at the same time inhibit the activity of ribonucleotide reductase. The specification has provided no assurances that such a fragment of Sml1 can have both characteristics of binding and inhibiting. Thus one of skill would be subject to undue experimentation without reasonable expectation of success in order to practice the broadly claimed methods and in order to make the pharmaceutical compositions as claimed.

4. All other rejections and objections as set forth in the previous Office action are withdrawn.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
11/15/2004

KAREN A. CANELLA PH.D
PRIMARY EXAMINER